XII. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

APR 13 2011

PROPREIETARY NAME:	DBX® Demineralized Bone Matrix Putty
COMMON NAME:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)
PROPOSED REGULATORY CLASS:	Class II
CLASSIFICATION IDENTIFICATION:	21 C.F.R. §888.3045 Resorable calcium salt bone void filler device
PRODUCT CODE:	MBP, MQV
SPONSOR:	Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 08837 732-661-0202

INDICATIONS FOR USE:

DBX Putty is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. DBX Putty is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury.

DBX Putty can be used alone in the posterolateral spine. DBX Putty can also be used as an extender in the spine with autograft or allograft. DBX Putty can be used with bone marrow. DBX Putty is for single patient use only.

DEVICE DESCRIPTION:

DBX Putty is composed of Demineralized Bone Matrix and sodium hyaluronate. The demineralized bone allograft in this product is prepared from tissue procured from a deceased donor using aseptic surgical techniques. The bone used in DBX Putty is cortical bone. Sodium hyaluronate is a naturally derived material that is biocompatible and biodegradable. The sodium hyaluronate is mixed in a phosphate buffered saline and is added to the demineralized bone to aid in maintaining physiological pH as well to improve the handling characteristics of demineralized bone.

SAFTEY AND EFFECTIVENESS INFORMATION:

This 510(k) was submitted for an addition to the indications for use of DBX® Putty in the posterolateral spine. Based on a recent *in vivo* study, DBX® Putty can be used as an extender in the spine with allograft. The fundamental scientific technology of the DBX® Putty with expanded indications for use in the posterolateral spine is the same as the technology for the predicate DBX® Putty (FDA cleared, K040262).

Biocompatibility of DBX® materials has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. DBX® is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

OSTEOINDUCTIVE POTENTIAL

DBX Demineralized Bone Matrix is osteoconductive, and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBX Putty product is tested in an athymic mouse model or in an alkaline phosphatase assay, which has been shown to have a positive correlation with the athymic mouse model, to ensure the osteoinductive potential of the final product. Standard testing performed in an athymic mouse or alkaline phosphatase assay must prove positive for lot release. It is unknown how the osteoinductive potential, measured in the athymic mouse model or the alkaline phosphatase assay, will correlate with clinical performance in human subjects.

VIRAL CLEARANCE AND INACTIVATION:

The method for processing the DBM contained in DBX® was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.

XII. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

PROPREIETARY NAME:	DBX® Demineralized Bone Matrix Inject
COMMON NAME:	Bone Void Filler Containing Human Demineralized Bone Matrix (DBM)
PROPOSED REGULATORY CLASS:	Class II
CLASSIFICATION IDENTIFICATION:	21 C.F.R. §888.3045 Resorable calcium salt bone void filler device
PRODUCT CODE:	MBP, MQV
SPONSOR:	Musculoskeletal Transplant Foundation 125 May Street Edison, NJ 08837 732-661-0202

INDICATIONS FOR USE:

DBX Inject is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. DBX Inject is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury.

DBX Inject can be used alone in the posterolateral spine. DBX Inject can also be used as an extender in the spine with autograft or allograft. DBX Inject can be used with bone marrow. DBX Inject is for single patient use only.

DEVICE DESCRIPTION:

DBX Inject is composed of Demineralized Bone Matrix and sodium hyaluronate. The demineralized bone allograft in this product is prepared from tissue procured from a deceased donor using aseptic surgical techniques. The bone used in DBX Inject is cortical bone. Sodium hyaluronate is a naturally derived material that is biocompatible and biodegradable. The sodium hyaluronate is mixed in a phosphate buffered saline and is added to the demineralized bone to aid in maintaining physiological pH as well to improve the handling characteristics of demineralized bone.

SAFTEY AND EFFECTIVENESS INFORMATION:

This 510(k) was submitted for an addition to the indications for use of DBX® Inject in the posterolateral spine. Based on a recent *in vivo* study, DBX® Inject can be used as an extender in the spine with allograft. The fundamental scientific technology of the DBX® Inject with expanded indications for use in the posterolateral spine is the same as the technology for the predicate DBX® Putty (FDA cleared, K040262).

Biocompatibility of DBX® Inject materials has been established through their long history of safe and effective clinical use, further supported by laboratory testing conducted per ISO 10993. DBX® Inject is single-donor processed using aseptic techniques and is tested for sterility per current USP <71>.

OSTEOINDUCTIVE POTENTIAL

DBX Inject is osteoconductive, and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBX Inject product is tested in an athymic mouse model or in an alkaline phosphatase assay, which has been shown to have a positive correlation with the athymic mouse model, to ensure the osteoinductive potential of the final product. Standard testing performed in an athymic mouse or alkaline phosphatase assay must prove positive for lot release. It is unknown how the osteoinductive potential, measured in the athymic mouse model or the alkaline phosphatase assay, will correlate with clinical performance in human subjects.

VIRAL CLEARANCE AND INACTIVATION:

The method for processing the DBM contained in DBX® Inject was evaluated for its viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Musculoskeletal Transplant Foundation
% Ms. Nancy Joy
125 May Street
Edison, New Jersey 08837

APR 13 2011

Re: K103795
Trade/Device Name: DBX® Demineralized Bone Matrix Putty and Inject
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: March 07, 2011
Received: March 10, 2011

Dear Ms. Joy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. INDICATIONS FOR USE

510(k) Number (if known): K103795

Device Name: DBX® Demineralized Bone Matrix Putty

Indications for Use:

DBX Putty is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. DBX Putty is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury.

DBX Putty can be used alone in the posterolateral spine. DBX Putty can also be used as an extender in the spine with autograft or allograft. DBX Putty can be used with bone marrow. DBX Putty is for single patient use only.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use _____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103795

IV. INDICATIONS FOR USE

510(k) Number (if known): K103795

Device Name: DBX® Demineralized Bone Matrix Inject

Indications for Use:

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Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103795